Report of UNICEF-WHO Consultation: Development of a Programming Guide for Scaling Up Treatment, Care and Support for HIV-Infected and Exposed Children in Resource-Constrained Settings New York City, USA:

January 11-13, 2006

Management Sciences for Health
is a nonprofit organization
strengthening health programs worldwide.

This report was made possible through support provided by the U.S. Agency for International Development, under the terms of Cooperative Agreement Number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

Helena Walkowiak

January 2006

Rational Pharmaceutical Management Plus
Report of UNICEF-WHO Consultation: Development of a Programming Guide for Scaling Up Treatment, Care and Support for HIV-Infected and Exposed Children in Resource-Constrained Settings
New York City, USA: January 11-13, 2006

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January 24, 2006

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About RPM Plus

The Rational Pharmaceutical Management Plus (RPM Plus) Program, funded by the U.S. Agency for International Development (cooperative agreement HRN-A-00-00-00016-00), works in more than 20 developing countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

Walkowiak, Helena 2006. *Report of UNICEF-WHO Consultation: Development of a Programming Guide for Scaling Up Treatment, Care and Support for HIV-Infected and Exposed Children in Resource Constrained Settings, New York City, USA: January 11-13, 2006.* Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Contents

Acronyms

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
EPI	Expanded Program on Immunization
FDA	Food and Drug Administration [United States]
HIV	human immunodeficiency virus
IMCI	Integrated Management of Childhood Illness
MSH	Management Sciences for Health
PCR	polymerase chain reaction
PMTCT	prevention of mother to child transmission [of HIV]
RPM	Rational Pharmaceutical Management Plus [Program]
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization

Background

While many countries in resource-limited settings have made considerable progress in scaling up access to HIV care and treatment for adults, the provision of services, especially antiretroviral therapy (ART) for children, is still in the early stages. The United Nations Children's Fund (UNICEF) and the World Health Organization (WHO) have agreed to develop appropriate programming guidance to assist countries in the scale up of pediatric HIV care and support.

The consultation was convened jointly by UNICEF and WHO with the following goal and objectives.

Goal—

- The aim of this meeting is to review the draft UNICEF / WHO programming guidance and identify essential revisions and modifications and outline next steps.

Specific Objectives—

1. Review and agree on the essential package of services for treatment, care and support of HIV-exposed and HIV-infected infants and children. This will include, but not be limited to:
    a. Routine HIV testing
    b. Follow up of children exposed to HIV and ensuring early testing (polymerase chain reaction [PCR] for infants and for older children, rapid antibody) through child and family care programs
    c. Delivery of long-term care of symptomatic children in health care settings, including provision of cotrimoxazole prophylaxis and ART
    d. Training to improve skill levels of health care providers and laboratory staff
    e. Delivery of home-based care to both exposed and infected children
    f. Provision of psychosocial support and counseling for HIV-infected children
    g. Quality improvement activities
2. Review the draft programming guidance to confirm its applicability, suitability, and relevance to the key intended audience.
3. To examine and endorse the identified key program elements of the draft programming guidance.

The terms of reference for the meeting are attached as Annex 1.

Scope of Work

Ms. Helena Walkowiak, Senior Program Associate, Management Sciences for Health (MSH) / Rational Pharmaceutical Management Plus (RPM Plus) Program attended the meeting at the UNICEF headquarters in New York City from January 11 to 13, 2006 to:

1. Give a presentation on experiences in improving supply management for pediatric HIV care and treatment in resource-constrained settings.

2. Participate in discussions and group work with other technical experts to review the draft programming guidance and develop a summary of recommendations to be reflected in the guidance, with a particular focus on supply management.

Activities

1. Give a presentation on experiences in improving supply management for pediatric HIV care and treatment in resource-constrained settings.

The agenda of the meeting is attached as Annex 2.

Ms. Walkowiak's presentation entitled *Experiences in Improving Supply Management for Pediatric HIV Care and Treatment in Resource-Constrained Settings* was very well received and is attached as Annex 3.

2. Participate in discussions and group work with other technical experts to review the draft programming guidance and develop a summary of recommendations to be reflected in the guidance, with a particular focus on supply management.

The following methodology was outlined by UNICEF and WHO for developing the draft recommendations—

- The draft programming guidance will be developed in a consultative manner involving relevant UNICEF and WHO technical and operational departments with the assistance of a consultant.
- The draft guidance will be shared with participants in advance of the consultation.
- Participants at the consultation will have the following profiles:
    - Experts in pediatric HIV care and support
    - Individuals from a select number of countries where demonstrable progress in delivery of HIV care and support has been made
    - National program managers or officers who would be the primary target audience of the programming guidance from countries where significant burden of pediatric HIV disease (either high prevalence or high total number of HIV infected women and children)
    - National or international partners with experience of effective approaches to providing pediatric HIV care and support
    - Individuals with program planning and implementation experience in related areas of child health, Expanded Program on Immunization (EPI), Integrated Management of Childhood Illness (IMCI) and prevention of mother to child transmission (PMTCT)
    - Individuals with health systems expertise; in particularly related to organization of health service delivery and human resource planning
- Participants at the meeting will review the priority intervention areas identified in the draft guidance document, identify through presentations and plenary discussion effective mechanisms for service delivery and key program requirements, and through group work provide recommendations to be incorporated in the finalized tools.

The list of participants is included as Annex 4.

Ms. Walkowiak was requested to act as co-chair for Group 3: Supplies (Forecasting and Management). The group used the Pharmaceutical Management Cycle to develop recommendations for the guide.

Observations of interest from a Pharmaceutical Management Perspective.

- Some participants felt that the Guidance should also address prevention in addition to treatment, care and support. It was frequently mentioned that in addition to rolling out ART for treatment that it is absolutely necessary not to lose focus on the need to strengthen PMTCT programs to prevent children becoming HIV-infected. There was a lot of discussion on building linkages between PMTCT and treatment / care.

- There was a great deal of discussion about where pediatric ART "fits" in health delivery – whether it should go with child health services or with the ART clinic. Generally, the feeling was that it would probably be both depending on the context, but the two challenges to both approaches are a) training staff in pediatric ART / HIV care and support and b) building systems to provide chronic care for children which do not generally exist in resources-constrained settings. Integrating HIV into IMCI was discussed in several presentations.

- There were several presentations and much discussion on the issue of diagnostics for children, including using PCR for diagnosis – several laboratories are investigating the utility of using a single PCR for diagnosis. Of particular interest to the pharmaceutical management staff is that none of the existing technologies are licensed by the United States Food and Drug Administration (FDA) to use PCR for diagnosis – this will be a major constraint to get approval to procure PCR technologies and even reagents for a non-FDA approved indication using funding under the U.S. President's Emergency Plan for AIDS Relief. Roche has not applied for FDA approval for this indication because they would like to build and obtain approval for one platform that will address the needs of adults and children so that countries do not have to buy both.

- Another laboratory issue related to monitoring for pediatrics is that the laboratory participants recommended that ideally one platform should be purchased to meet the needs of both adults and children. E.g. CD4 machines should be able to do CD4 / CD8 percentages in addition to CD4 / CD8 absolute values; other automated equipment should be able to handle small sample volumes in addition to larger samples for adults. There was also a lot of discussion on using dried blood spots so that samples can be sent to wherever the equipment is located, (including in some cases other countries).

- Although there was only one presentation that focused on supply management (given by Ms. Walkowiak) supply management was mentioned in many of the presentations, especially in the country experiences, as a major constraint to implementation.

- A major focus of the supply management discussion for participants appeared to be on producing reliable forecasts for the pharmaceutical industry for pediatric ART and also for cotrimoxazole. This appears to be an area of focus for UNICEF and WHO and participants were particularly interested in what tools and methodologies exist to improve forecasting at the country level and how to make them more available to countries.

- There was also much discussion of the need for accurate consumption data for pediatric ART and information on scale up to inform forecasting. Again participants were interested in available software and technologies to capture, analyze and report data on pediatric ARVs and medicines to prevent and treat opportunistic infections at the site level.

Collaborators and Partners

The list of participants is attached as Annex 4.

Next Steps

UNICEF and WHO representatives stated that they would like to continue to work with partners to develop and finalize the guide. MSH/RPM may receive further requests to comment as the draft develops. RPM Plus will work with United States Agency for International Development (USAID) to explore opportunities for future collaboration to support the scale up of pediatric HIV care and treatment.

Annex 1. Meeting Terms of Reference

WHO/UNICEF-sponsored consultation to support development of a programming guide for HIV related treatment, care and support for HIV-infected and exposed children in resource-constrained settings

I. Background / Rationale:

Many countries are now in the early stages of scaling up the provision of pediatric HIV care, support, and treatment, and while many have already made progress with scaling up adult HIV care and support programs, few have made significant progress to ensure HIV care and ART is provided to children. Few countries have more than a few tertiary-level sites with the capacity to provide HIV-related care and support for the child or the entire family. Many stakeholders at national level have expressed the need for better guidance on how best to scale up the provision of care and support for HIV-infected children, particularly in the context of resource-constrained settings, and for information on how to integrate this guidance with existing child survival and PMTCT program efforts. UNICEF and WHO have agreed to develop appropriate programming guidance to assist countries in the scale up of pediatric HIV care and support.

This meeting is designed to review key elements of the draft proposed programming guidance and examine it in relation to available evidence and programmatic experience.

II. Goals: The aim of this meeting is to review the draft UNICEF/WHO programming guidance and identify essential revisions and modifications and outline next steps.

III. Specific Objectives:

4. Review and agree on the essential package of services for treatment, care and support of HIV-exposed and HIV-infected infants and children. This will include, but not be limited to:
    a. Routine HIV testing
    b. Follow up of children exposed to HIV and ensuring early testing (PCR for infants and for older children, rapid antibody) through child and family care programs
    c. Delivery of long-term care of symptomatic children in health care settings, including provision of cotrimoxazole prophylaxis and antiretroviral therapy
    d. Training to improve skill levels of health care providers and laboratory staff

e. Delivery of home-based care to both exposed and infected children
f. Provision of psychosocial support and counseling for HIV-infected children
g. Quality improvement activities

5. Review the draft programming guidance to confirm its applicability, suitability, and relevance to the key intended audience.
6. To examine and endorse the identified key program elements of the draft programming guidance.

IV. Methodology

a. The draft programming guidance will be developed in a consultative manner involving relevant UNICEF and WHO technical and operational departments with the assistance of a consultant.

b. The draft guidance will be shared with participants in advance of the consultation.

c. Participants at the consultation will have the following profiles:

a. Experts in pediatric HIV care and support
b. Individuals from a select number of countries where demonstrable progress in delivery of HIV care and support has been made
c. National program managers or officers who would be the primary target audience of the programming guidance from countries where significant burden of pediatric HIV disease (either high prevalence or high total number of HIV infected women and children)
d. National or international partners with experience of effective approaches to providing pediatric HIV care and support.
e. Individuals with program planning and implementation experience in related areas of child health, EPI and IMCI and PMTCT
f. Individuals with health systems expertise; in particularly related to organization of health service delivery and human resource planning

d. Participants, at the meeting will review the priority intervention areas identified in the draft guidance document, identify through presentations and plenary discussion effective mechanisms for service delivery and key program requirements, and through group work provide recommendations to be incorporated in the finalized tools.

V. Expected output: The meeting will develop a summary of recommendations that will need to be reflected in revisions to content, scope, and format of the programming guidance being developed.

VI. Meeting participants:

- **International Organizations**
  - UNICEF
  - WHO

- **Implementing partners**
  - ANECCA
  - Basics
  - Baylor Pediatric AIDS Initiative
  - Catholic Medical Mission Board
  - Catholic Relief Services
  - Center for International Health
  - Clinton Foundation
  - Columbia University
  - Community of Sant Egidio – DREAM Program
  - EGPAF
  - FHI
  - Forum on Collaborative HIV Research – George Washington University
  - Global AIDS Alliance
  - Human Sciences Research Council
  - International HIV/AIDS Alliance
  - Medical Missions for Children
  - MSF
  - MSH
  - Partners in Health
  - Population Council
  - Save the Children UK
  - Save the Children US
  - The FORUM – George Washington University
  - UNC – Chapel Hill

- **Funding Institutions**
  - CDC
  - NIH
  - USAID

- **Pharmaceutical Companies**
  - Johnson & Johnson
  - Pfizer, Inc.
  - Roche Molecular Systems

- **Representatives from countries where significant progress has been made.**
  - Brazil
  - South Africa
  - Thailand

- **Countries with high burden overall (either prevalence or numbers or both)**
  - Botswana
  - Cameroon
  - China
  - Ethiopia
  - South Africa
  - Uganda
  - Ukraine
  - Zimbabwe

VII. Date and Venue

Venue: UNICEF Headquarters
Date: January 11 – 13, 2006

VIII. Language: English

IX. Administrative Arrangements

- UNICEF will make arrangements for conference facilities and accommodations
- UNICEF/WHO will send out formal invitations to all participants
- UNICEF and WHO will ensure participation of appropriate UNICEF and WHO field staff.
- UNICEF/WHO will engage the services of a consultant for preparation and revision of the draft programming guidance and supervise his/her work until completion.

Annex 2. Agenda

UNICEF-WHO CONSULTATION
DEVELOPMENT OF A PROGRAMMING GUIDE FOR SCALING UP TREATMENT, CARE AND SUPPORT FOR HIV-INFECTED AND EXPOSED CHILDREN IN RESOURCE-CONSTRAINED SETTINGS

January 11 - 13, 2006
UNICEF House, 3 United Nations Plaza
New York City

Wednesday, January 11th, 2006 (Day 1)

8:00 – 9:00 **Registration**

Session 1: Introductions and Review of the Current Situation
Chair: L. Mofenson, National Institutes of Health
Rapporteur: R. Ferris, USAID

9:00 – 9:30 **Welcome and Opening Remarks**
P. McDermott

9:30 – 9:45 **Setting the scene: Why we are concerned**
C. Luo

9:45 – 10:00 **Positioning HIV in Children into the Child Survival Agenda**
L. Mason

10:00 – 10:15 **Setting Targets: Why, How, and Which?**
C. Gilks

10:15 – 10:30 **Moderated Discussion**
Session Chair

10:30 – 10:45 **Break**

Session 2: Optimizing Entry into Care: Finding Children in Need
Chair: M. Kline, Baylor College of Medicine
Rapporteur: Susan Fiscus, UNC – Chapel Hill School of Medicine

10:45 – 11:05 **Optimizing Entry into Care: Finding Children in Need**
G. Tene

11:05 – 11:25 **Institutionalizing Early Diagnosis in a Public Health Model**
G. Sherman

11:25 – 11:45	**Early Diagnosis: Recommendations from ANECCA Consultation** B. Eley
11:45 – 12:05	**Early Diagnosis: Experiences from Rwanda and Botswana** T. Creek
12:05 – 12:25	**Technical Recommendations for follow-up of HIV-exposed and infected infants** S. Crowley
12:25 – 12:45	**Follow-up of Infants: Linkages between PMTCT and Care** E. Abrams
12:45 – 1:00	**Questions**
1:00 – 2:00	**Lunch**
2:00 – 2:45	**Moderated Discussion** Session Chair

Session 3: Management of HIV-exposed and HIV-infected Children
Chair: R. Mathai, Catholic Medical Mission Board
Rapporteur: B. Pazvakavambwa, WHO

2:45 – 3:05	**The IMCI Approach – A focus on follow up of HIV-exposed and HIV-infected infants** L. Muhe
3:05 – 3:25	**The IMAI Approach – A chronic HIV care model** S. Gove
3:25 – 3:45	**The Ugandan Experience with IMCI and IMAI** K. Mugisha
3:45 – 4:00	**Break**
4:00 – 4:30	**Moderated Discussion** Session Chair
4:30 – 4:50	**Infant and Young Children Feeding Strategies for HIV-exposed Children** L. Mason
4:50 – 5:10	**The Ghanaian Experience with Infant Feeding for HIV-exposed Children** A. Akuomoa- Boateng

5:10 – 5:45 **Moderated Discussion**
Session Chair

Thursday, January 12th, 2006 (Day 2)

Session 4: Strategies for Scaling Up
Chair: M. Anderson, Center for International Health
Rapporteur: J. Riehl, Medical Missions for Children

8:30 – 8:45 **Welcome**

8:45 – 9:05 **The Rwandan Experience: Scaling up Pediatric Treatment**
D. Gashumba

9:05 – 9:25 **The Ukrainian Experience: Care for Special Populations**
S. Komar

9:25 – 9:45 **The Thai Experience: HIV M&E and QI for Children**
A. Teeraraktul

9:45 – 10:05 **Break**

10:05 – 10:25 **The Ugandan Experience: Capacity Building**
I. Kalyesubula

10:25 – 10:45 **The African Experience: Supply Management**
H. Walkowiak

10:45 – 11:05 **Overview of Strategies for Scaling Up**
R. Gass

11:05 – 12:00 **Moderated Discussion of Scale Up Strategies**
Session Chair

12:00 – 1:00 **Lunch**

Session 5: Community-based Interventions
Chair: J. Mukherjee, Partners in Health
Rapporteur: C. Abate, Catholic Relief Services

1:00 – 1:20 **Community Based Strategies for Treatment, Care and Support for HIV-Infected and Exposed Children**
R. Lovich

1:20 – 1:40 **Home-based Care for Children: The S. African Experience**
L. Scheepers

1:40 – 2:10 **Moderated Discussion of Community-based Interventions**
Session Chair

Session 6A: Group Work

2:45 – 3:00 **Introduction to Programming Guide and Group Work**
R. Gass

2:10 – 2:45 **Review of Draft Programming Guide**
J. Pinto

3:00 – 3:15 **Break**

3:15 – 5:30 **Group 1: National Leadership, Program Management, Coordination, Planning, Target Setting**
Chair: Y.D. Mukadi, Institute for HIV/AIDS, FHI
Rapporteur: N. Ngongo, UNICEF

3:15 – 5:30 **Group 2: Operational Structure for Program Delivery**
Chair: D. Silimpieri, BASICS
Rapporteur: G. Kumar Nair, Save the Children UK

3:15 – 5:30 **Group 3: Pediatric-related Supplies (Forecasting and Management)**
Chair: B. Cheng, Forum on Collaborative Research, GW University
Rapporteur: A. Reinisch, WHO

3:15 – 5:30 **Group 4: Identification, Care, Support and Treatment Interventions for Exposed Infants and Infants of Unknown Status**
Chair: M. P. Kieffer, CDC - Kenya
Rapporteur: D. Buyse, UNICEF

3:15 – 5:30 **Group 5: Care package of interventions for Infected Children**
Chair: C. Wilfert, Elizabeth Glaser Pediatric AIDS Foundation
Rapporteur: S. Kumar, UNICEF

3:15 – 5:30 **Group 6: Strengthening Community-based Delivery of Care, Support and Treatment for Exposed and Infected Children**
Chair: A. Bartlett, USAID
Rapporteur: E. Kebede, WHO

5:30 – 7:30 **Reception**
UNICEF House

Friday, January 13th, 2006 (Day 3)

Session 6B: Group Work

9:00 – 12:00	**Group Work Continued**	
12:00 - 1:00	**Lunch**	

Session 7: Plenary

1:00 – 3:00	**Report Back from Groups** **Chair: P. Villeneuve** **Rapporteurs: J. Pinto and A. Reinisch**	
3:00 – 3:30	**Discussion of Next Steps and Closing Session**	P. McDermott **C. Gilks**

Annex 3. Presentation on *Experiences in Improving Supply Management for Pediatric HIV Care and Treatment in Resource-Constrained Settings*: Helena Walkowiak, RPM Plus

Experiences in Improving Supply Management for Pediatric HIV Care and Treatment in Resource-Constrained Settings

Helena Walkowiak
January 12, 2006

MSH Management Sciences for Health
RPM Plus | Rational Pharmaceutical Management Plus
USAID

Presentation Outline

Share experiences and lessons learned in improving supply management for pediatric HIV care and treatment in resource-constrained settings—

- Selection of medicines and diagnostics
- Forecasting needs
- Coordinated procurement and distribution
- Flexible and responsive supply systems
- Pharmaceutical Management Information Systems

MSH Experience in Strengthening Pharmaceutical Management for HIV/AIDS Programs

- In 2002, MSH / RPM Plus Program began assisting the Government of Kenya to establish ART learning sites in Mombasa, in partnership with FHI / IMPACT and Population Council / Horizons
- MSH is currently providing technical assistance in pharmaceutical management to assist governments to roll out ART with USG funding in—
  - Africa: Ethiopia, Kenya, Ivory Coast, Malawi, Namibia, Rwanda, South Africa, Tanzania, Zambia
  - Caribbean: Guyana, Haiti
  - Asia: Vietnam

Selecting Medicines and Diagnostics

- STGs provide the basis for successful forecasting of needs, procurement and supply management
- Pediatric ART STGs
  - Forecasting can be simplified if STGs include—
    - Drugs and regimens
    - Weight band dosing charts by formulation
    - Preferred formulation for age / weight band
    - Guidance for ART experienced children
    - Recommendations for laboratory monitoring
  - Require frequent updating – new science, changing market
  - Will determine needs for oral syringes, spoons, tablet cutters, and containers for dispensing
- National Laboratory Policy and Strategic Plan determine—
  - Level / facilities where laboratory tests / technologies are to be available
  - Time frame for roll out

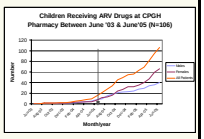
Selection: Country Experiences – Kenya (1)

- ART STGs
  - Guidelines to Antiretroviral Drug Therapy in Kenya
    - 1st edition February 2001, 2nd edition February 2002
      - Specified regimen, drug and per kg / m^2 dosing
  - Kenyan National Clinical Manual for ARV Providers
    - 1st edition April 2004
      - Dosing algorithm by weight / surface area for each formulation listed
      - Recommendations on splitting solid preparations
    - 2nd edition in print
      - Laboratory monitoring for pediatric ART

- National Laboratory Policy and Strategic Plan
  - Drafted in 2005; plan to finalize 2006

Selection: Country Experiences – Kenya (2)

- Impact of ART STGs at national level
  - Reported to have assisted in forecasting of needs
  - Early days but initial reports from field indicate improvements in supply management
- Impact of ART STGs at Coast Provincial General Hospital (CPGH), Mombasa
  - New dosing guidelines implemented August 2004
  - Recruitment – average number of new patients per month increased from 2 (Feb 04 to Jul 04) to 5 (Aug 04 to June 05)
  - Decreased storage needs for scale up
  - Reported to have simplified medication counselling at pharmacy and ART clinic



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Forecasting of Pediatric HIV Medicine Needs

- Complex
- Scientific field is still developing
- Dynamic market – new products, product shortages, long lead times, ongoing WHO prequalification and FDA-approval
- Short shelf life, limited product stability after reconstitution
- Rate of scale up is limited by capacity to diagnose HIV infection and deliver ART services
- Knowledge of the regimen does not automatically translate into specific products or dispensing quantities
- Information on age, weight and / or surface area is required to calculate doses
- Different dosing recommendations exist
- Adjustments are necessary for growth and weight gain in children who continue ART

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Coordination: Country Experiences – Rwanda

- Coordination done by Resource Management Commission
  - Quantification Committee
    - Estimation of needs / budgets per program for a procurement period
    - Review assumptions
    - Identify barriers to quantification process; provide recommendations
  - Procurement and Distribution Committee
    - Oversee procurement processes
    - Develop / implement distribution plans
    - Monitor / report distribution
  - Therapeutics Committee
    - Promote common strategies to promote adherence to STGs
    - Inform on issues that might affect consumption patterns
- Integrated Supply: CAMERWA
- Impact of coordination
  - 2005 donation from CHAI organized in staggered deliveries

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Improving Forecasting of Needs: Country Experiences and Lessons Learned

- Coordination and teamwork at national and local level in place in some countries assist in—
  - Sharing new science, market intelligence, epidemiological data sets / consumption data sets and successful methodological approaches
  - Developing and improving accuracy of assumptions
- Tools and methodologies—
  - Demand Forecasting Tool – Clinton HIV/AIDS Initiative (CHAI)
  - Quantification spreadsheet used in Western Cape, South Africa
  - Quantimed – RPM Plus
    - Pharmaceutical Quantification and Cost Estimation Tool
    - Used for ARV procurement planning and budgeting for PEPFAR activities in Haiti, Namibia, Rwanda, Kenya and Zambia

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Coordination: Country Experiences – Kenya

- Coordination done by NASCOP
  - Subcommittees have an advisory role
  - Recommendations of the subcommittee are ratified and forwarded by NASCOP to MoH for implementation
- Pediatric ART Steering Committee
  - Recently established – MOH, donors and private sector
  - Mandate to deal with all pediatric ART issues
- Medicines Subcommittee
  - MOH, donors, facility staff, KEMSA
  - Responsibilities
    - Determine standard first-line and second-line regimens for ART
    - Drug quantification
    - Drug distribution planning
    - Drug quality assurance
    - Support efficient data collection, analysis and reporting by sites
- Integrated Supply: KEMSA, MEDS

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Why Coordinate Procurement and Distribution of HIV Medicines?

- Effectiveness
  - Avoid ARV stock outs; ensure availability
  - Ability to rapidly respond to changes in protocol use, scale up
- Efficiency
  - Avoid duplication
  - Single national buffer stock
- Expense
  - Cost implications of slight inefficiencies

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Lesson Learned: Key Elements to Support the Coordination System

- Transparent and inclusive process
- Identification of key players
  - Definition of roles and responsibilities
  - Establishment of forums to discuss, share information, make decisions
- Definition of key processes to support the system
- Flexibility to allow donors to observe different procurement rules
  - Limits harmonization of products and standardization of procedures
  - Coordination of a multi-route procurement process crucial
- Monitoring, reporting and evaluation
- Technical support and capacity building

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Flexible and Responsive Supply Systems: Possible New Approaches

- At national level, a fully funded, supported and active pharmaceutical management unit to manage ARVs from all sources
- Regularly updated, pre-purchasing information and forecasting provided to the marketplace, and active liaison with the manufacturers
  - Information on WHO-prequalified and FDA-approved products
    - White List for ARV Procurement – CHAI
    - WHO prequalification - http://mednet3.who.int/prequal/
    - FDA website http://www.fda.gov/oia/pepfar.htm
- Active supply pipeline information systems and management
- Consideration to harnessing private sector resources
- Lean stock holding, distribution systems requiring higher frequency deliveries, and a dynamic and very accurate pharmaceutical MIS

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Pharmaceutical Management Information Systems

- Inaccurate or lack of ART data is universally identified as a major constraint to successful quantification for ART programs
- For pediatric ART
  - Need data on:
    - Consumption for quantifying needs for existing patients including adjustments for growth / weight gain
    - Current rate and profile of scale up by regimen and formulation for forecasting needs for scale up
    - Changes by regimen and product
    - Information on factors that may impact scale up
    - Patient-focused data for pharmaceutical care e.g. monitoring adherence
  - Difficult to extract data needed from manual tools
- Data for OI use in pediatrics is rarely available
- Sites need simple tools (including simple software) and assistance to collect, analyze and report data

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Flexible and Responsive Supply Systems: Country Experiences – Vietnam

- New ARV management unit at Vietnam Administration for AIDS Control under discussion
- PEPFAR currently procures all pediatric ARVs
  - 5 procurements in 2005
  - Each procurement was amended to meet changing circumstances on the ground
- Treatment sites report monthly
- ART Inventory Tracking Tool – RPM Plus
  - Facilitates the management of ARVs and OI medicines at an aggregate level; tracks expected influx, estimated monthly demand, and number of patients by regimen and facility
- Monthly meeting of all active players
  - To review ARV stock levels / uptakes
  - Reschedule allocations, future predictions and funding requirements
  - Extended to OI drugs
- Use parastatal / private sector storage and distribution

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Pharmaceutical Management Information Systems: Country Experiences

- Data Collection Tools
  - ARV Dispensing Tool – RPM Plus
    - Links patient information and individual ART history to stock movement in a facility
    - Maintains records for each patient receiving ART - tracks patient profile and medication history
    - Generates key management reports, such as Monthly Patient Uptake Trends and Currently Active Patients per Regimen
    - Experiences
      - Cote d'Ivoire: 11 sites
      - Haiti: 4 sites
      - Kenya: 20+ sites
      - Namibia: 4 sites
      - Rwanda: 5 sites
      - Tanzania: 1 site
      - Zambia: 17 sites
  - Others

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Flexible and Responsive Supply Systems: Country Experiences – Kenya

- ARV procurement and distribution coordinated by NASCOP
- Procurement and distribution
  - Both public and private (not-for-profit) systems are used to procure and distribute ARVs to meet targets for scale up
  - Private sector (MEDS) requests flexible delivery schedules depending on actual needs by sites; additional purchase orders have been placed to deal with surges in demand
  - Public Sector (KEMSA) restricted by procurement regulations to delivery in one consignment
- Treatment sites report monthly on consumption and stock status
- ART Inventory Tracking Tool – used by MEDS
- Regular meeting of all active players
  - Exchange market information
  - Review stock status, forecasted and funding requirements

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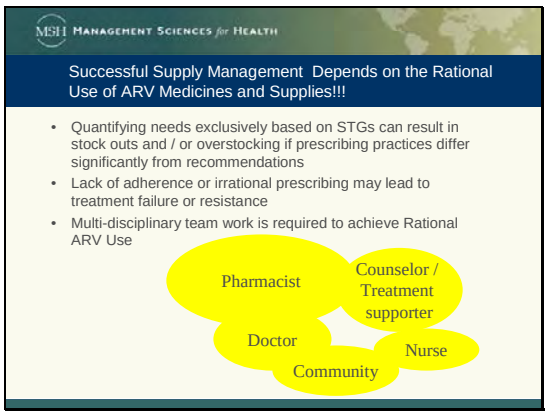
Summary

- Too early in many pediatric ART programs to see impact
- However indications are that promising approaches to improve supply management for pediatric ART are being developed to—
  - Guide selection of ART regimen, formulations, dosing and laboratory monitoring
  - Improve accuracy of forecasting
  - Coordinate procurement and supply
  - Develop flexible and responsive supply systems
  - Improve reliability and timeliness of data collection and reporting


MSH Management Sciences for Health
Successful Supply Management Depends on the Rational Use of ARV Medicines and Supplies!!!
• Quantifying needs exclusively based on STGs can result in stock outs and / or overstocking if prescribing practices differ significantly from recommendations
• Lack of adherence or irrational prescribing may lead to treatment failure or resistance
• Multi-disciplinary team work is required to achieve Rational ARV Use
Pharmacist
Counselor / Treatment supporter
Doctor
Nurse
Community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Strengthening pharmaceutical management for better health worldwide
USAID

Annex 4. Meeting Participants

Name	Organization	Title
Abrams, Elaine	Columbia University	Professor of Pediatrics & Epidemiology
Abate, Carmela	Catholic Relief Services	Senior Regional Technical Advisor Health & HIV; Regional Coordinator East Africa
Agarwal, Arpana	Clinton Foundation	Programme Manager
Akuamoa-Boateng, Abenaa	Ashanti Regional Health Directorate - MoH	Regional Nutrition Officer
Akwara, Priscilla	UNICEF, HQ	Project Officer
Alnwick, David	UNICEF ESARO	Regional Adviser, HIV/AIDS
Anabwani, Gabriel	Botswana-Baylor Children's Clinical Centre of Excellence	Clinical Professor of Pediatrics and Executive Director
Anderson, Mark	Center for International Health	President
Bartlett, Al	USAID, Office of Health, Infectious Diseases, and Nutrition	Senior Advisor for Child Survival
Bowsky, Sara	USAID, Bureau for Africa	HIV/AIDS Care Advisor
Buyse, Dirk Stefaan	UNICEF (Western & Central Africa Regional Office)	WCARO PMTCT/HIV
Calles, Nancy	Baylor International Pediatric AIDS Initiative	Vice-President, International Program Development
Cheng, Ben	George Washington University	Deputy Director, Forum on Collaborative HIV Research
Creek, Tracy	CDC	Medical Officer; PMTCT Team
Crowley, Siobhan	WHO	Treatment, Prevention & Scale-Up Team, HIV/AIDS
Damonti, John	Bristol-Myers Squibb Company	
DeGennaro, Vince	Global AIDS Alliance	Medical Student Advocacy Fellow
Dladla, Nobayeni	Embassy of South Africa	Health Attache
Ekpini, Rene	WHO	Technical Officer/PMTCT
Eley, Brian	University of Cape Town, Red Cross Children's Hospital	Head: Infectious Diseases
Engle, Patrice	UNICEF, HQ	Senior Advisor, Integrated Early Childhood Development
Essajee, Shaffiq	The Clinton Foundation	Senior Advisor in Pediatrics
Fakoya, Ade	International HIV/AIDS Alliance	Senior Programme Officer for Clinical Care
Farmer, Mychelle	Catholic Relief Services	HIV/AIDS Programming
Ferris, Robert	USAID GH/OHA/TLR	Medical Transmission Manager
Field-Nguer, Mary Lyn	BASICS Project, JSI	Director, HIV/AIDS Programs, JSI/DC/Pediatric AIDS Advisor, BASICS Project
Filatova, Ekaterina	WHO EURO	Technical Officer/PMTCT, Child and Adolescent Health and Development
Fiscus, Susan	UNC - Chapel Hill School of Medicine	Professor of Microbiology & Immunology
Futterman, MD, Donna	Mothers Programmes	Board Member Director, Adolescent AIDS Program
Gashumba, Diane	University Hospital of Kigali	Pediatrician

Name	Organization	Title
Gass, Robert	UNICEF, HQ	Project Officer, HIV/AIDS Care and Support
Gilks, Charlie	WHO	Director/Coordinator TPS, HIV/AIDS
Goings, Stella	USAID: Bureau for Africa	Principal Advisor, HIV/AIDS
Gotink, Marinus	UNICEF, South Africa	Health & Nutrition
Gove, Sandy	WHO	IMAI Team, HIV/AIDS
Guidotti, Giovanni	Community of Sant'Egidio - DREAM program	Programme Manager: Mozambique, Kenya and Tanzania
Hattingh, Lucy	Virology - HIV; Roche Molecular Systems, Inc	Director of International Marketing
Kaluwa, Owen	WHO, Botswana	HIV/AIDS Country Officer
Kalyesubula, Israel	Mulago Hospital, Department of Paediatrics and Child Health	Consultant Paediatrician
Kamau, Macharia	UNICEF, South Africa	Country Office Representative
Kebede, Eyerasalem	WHO Country Office in Ethiopia	NPO/IMCI/WHO
Kebede, Senait	WHO - AFRO	Focal person on Pediatric Care
Kenya-Mugisha, Nathan	Masaka Regional Hospital	Medical Superintendent
Khalil, Samir A.	Merck & Co., Inc.	Executive Director, HIV Policy & External Affairs
Kieffer, Mary Pat	Deputy Director, Office for Regional HIV/AIDS Programs - USAID / REDSO-ESA	Senior Regional Advisor for PMTCT and Pediatric AIDS
Kline, Mark	Baylor International Pediatric AIDS Initiative	Professor and President
Knippenberg, Rudolf	UNICEF HQ	Senior Adviser Health
Kola, Rihanna	Merck & Co., Inc.	Director of External Affairs; Human Health International
Komar, Svitlana	Ukrainian AIDS Centre	Consultant on paediatric ARV treatment
Kumar Nair, Gopa	Save The Children	HIV AIDS adviser SCF UK
Kumar, Smita	UNICEF, HQ	Consultant, PMTCT & Pediatric HIV/AIDS
Liotta, Giuseppe	Community of Sant'Egidio - DREAM program	Head of Clinical Services – Malawi
Lovich, Ronnie	Save The Children	Sr. HIV/AIDS Advisor
Luo, Chewe	UNICEF, HQ	Senior Health Advisor
Mahy, Mary	UNICEF HQ	Programme Officer, Division of Policy & Planning
Mannion, Bill	Pfizer Inc., International Philanthropy	Assistant Director, Global HIV/AIDS Initiatives
Mason, Liz	WHO	Director of Child and Adolescent Health
Mathai, Rabia	Catholic Medical Mission Board (CMMB)	Senior Vice President - Global Program Policy, Planning, Strategic Partnerships
Mbewe, Andrew L.	WHO Regional Office for Africa	AFRO RO Child Health HIV adviser
McDermott, Peter	UNICEF, HQ	Chief, HIV/AIDS Section
McGoldrick, John	Bristol-Myers Squibb Company	
Meng Zhao, Zhaoyan	NCAIDS, China CDC	Supervises Pediatric Free ART
Mizwa, Michael	Baylor International Pediatric AIDS Initiative	Vice-President, International Affairs

Name	Organization	Title
Mofenson, Lynne	National Institutes of Health	Branch Chief
Muhe, Lulu Mussa	WHO	Medical Officer, Child & Adolescent Health and Development
Muita, Jane	UNICEF - Rwanda	Project Officer HIV/AIDS
Mukadi, Ya Diul	Institute for HIV/AIDS, Family Health International	Director of Care and Treatment Division
Mukherjee, Joia	Partners in Health	Internist and AIDS specialist, Pediatrician
Mulenga, Doreen	UNICEF, HQ	Senior Advisor
Ngongo, Ngashi	UNICEF, HQ	HIV Care & Support Advisor
Olson, David	Medicins Sans Frontieres	Medical Advisor
Ou, Chin-Yih	CDC - Atlanta	Microbiologist, NCHSTP/GAP
Oyegbite, Kayode	UNICEF, HQ	Senior Programme Officer
Pazvakavambwa, Brian	WHO, AFRO	InterCountry Programme on HIV/AIDS for Southern Africa (AFRO/ICP/HIV/SA)
Pederson, Hanne Bak	UNICEF - Copenhagen	Chief Technical Services
Pinto, Jorge	Federal University of Minas Gerais	Consultant, Pediatric HIV/AIDS; Associate Professor, Chief of Pediatric Immunology Division
Ratzan, Scott	Johnson & Johnson	Vice President, Pharmaceuticals and Global Health
Reinisch, Annette	WHO/UNICEF	Pediatric HIV care Consultant
Riehl, John	Medical Missions for Children	Executive Vice President
Rivadeneira, Molly (Emilia)	CDC - Global AIDS Program	Medical Officer; HIV Care and Treatment Team
Rosenfield, Allan	Columbia University	Dean/Director of Mailman School of Public Health
Rutenberg, Naomi	Population Council	Program Director, Horizons
Scheepers, Lorna	Department of Health - South Africa	Community Based Care Manager
Sherman, Gayle	National Health Laboratory Service, University of the Witwatersrand	Associate Professor: Paediatric Haematology
Silimperi, Diana R.	BASICS	Technical Director
Stecker, Carl	Catholic Relief Services	Director of HIV/AIDS Treatment
Tawfik, Youssef	USAID	Child Health Advisor
Teeraratkul, Achara	CDC/GAP (Thailand)	Chief, Surveillance, Monitoring and Evaluation Section
Tene, Gilbert	Chantal BIYA Foundation in Yaounde, Cameroon	Pediatrician
Terreri, Nancy	UNICEF, HQ	Senior Health Advisor
Villeneuve, Pascal	UNICEF, HQ	Chief, Health Section
Walkowiak, Helena	Management Sciences for Health	Pharmacist, HIV/AIDS technical assistant
Wilfert, Cathy	Elizabeth Glaser Pediatric AIDS Foundation	Scientific Director
Xundu, Nomonde	Embassy of South Africa	Cluster Manager: HIV and AIDS
Zeitz, Paul	Global AIDS Alliance	Executive Director